## REMARKS

Claims 1-9 are pending in the subject application and are subject to a restriction requirement.

### Requirement for restriction under 35 U.S.C. 121

In the September 8, 2003 Office Action, the Examiner required restriction under 35 U.S.C. § 121 to one of the following allegedly independent and distinct inventions:

Groups 1-4,083. Claims 1-3 and 9, insofar as the claims are drawn to a composition comprising at least two immunogenic ligands, wherein said ligands are selected from the group consisting of SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 9, SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 15, SEQ ID NO: 17, SEQ ID NO: 19, SEQ ID NO: 21, SEQ ID NO: 23, and SEQ ID NO: 25, and a method for inducing an immune response comprising delivering to a subject said composition, classified in class 424, subclass 185.1.

Upon election of Groups 1-4083, the Examiner requires further election of a single disclosed invention by identifying the specific composition comprising at least two of the recited ligands to which the claims are to be drawn during examination.

Groups 4,084-8,166. Claims 4-8, insofar as the claims are drawn to a host cell comprising at least two immunogenic ligands, wherein said ligands are selected from the group consisting of SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 9, SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 15, SEQ ID NO: 17, SEQ ID NO: 19, SEQ ID NO: 21, SEQ ID NO: 23, and SEQ ID NO: 25, classified in class 435, subclass 325+, for example.

Upon election of Groups 4084-8166, the Examiner requires further election of a single disclosed invention by identifying the specific host cell comprising at least two of the recited ligands to which the claims are to be drawn during examination.

**Request for reconsideration of restriction requirement under 37 C.F.R. 1.143**

Applicants respectfully request a reconsideration and modification of this restriction requirement. The presently claimed inventions are drawn to compositions selected from 12 specifically defined peptide sequences, host cells comprising compositions selected from 12 specifically defined peptide sequences, and methods utilizing compositions selected from 12 specifically defined peptide sequences. By setting forth 8,166 groups from these claims, the instant restriction is unreasonable and inconsistent.

The Office has recently instituted a policy directed to improving restriction practice within TC 1600 as stated by the recent publication of the TC1600 Restriction Practice Action Plan (press release on October 6, 2003). This policy emphasizes the importance of the quality and consistency of restriction practice and recognizes the need for improvements in this complex technology unit. Pertinent to this policy, Applicants point out that the instant restriction is inconsistent with previously issued restriction requirements for subject applications containing similar types of claim sets[1].

As stated by the Office, there are two criteria for a proper requirement for restriction between patentably distinct inventions, MPEP 803. First, the inventions must be independent or distinct. Second, there must be a serious burden on the Examiner if

[1] The restriction requirement issued in application no. 09/862,260 on 16 July 2002 (enclosed in this communication as Appendix I) found 3 allegedly distinct inventions as contrasted with the 8,166 alleged by the instant restriction requirement. The restriction requirement issued in application no. 09/870,089 on 22 August 2003 (enclosed in this communication as Appendix II) found 288 allegedly distinct inventions as contrasted with the 8,166 alleged by the instant restriction requirement . This inconsistency is notable due to the similarity in the claim sets under prosecution in each application.

restriction is required. The Examiner must examine the subject application on the merits even if it includes claims to distinct inventions if such an examination can be made without serious burden. Applicants assert that the search of claims 1-9 does not comprise such a serious burden that restriction into 8,166 inventions is proper.

Independent claims 1, 4, and 9 each contain a Markush grouping comprising 12 specifically defined peptide sequences. According to MPEP § 803.02. the Examiner must examine all members of the Markush group in the claims on the merits even if they are directed to independent and distinct inventions, if the examination can be made without serious burden.

> "If the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions." MPEP § 803.02.

Applicants assert that these independent claims 1, 4, and 9 can be searched without serious burden.

First, the Office is capable of readily performing sequence searches of peptide sequences. The peptide sequences present in the instant claims are relatively uncomplicated. They uniformly consist of only 9 amino acids. Many sequences share related characteristics such as shared anchor residues, e.g. SEQ ID NOS 3 and 5; or SEQ ID NOS 19 and 21. Additionally, Applicants have provided sequence listings for the instant sequences. These factors indicate that an examination of the peptide sequences contained in the Markush group of the instant claims can be reasonably performed.

Second, Applicants note that chemical cases with Markush groups, which often contain complicated chemical R group structures, are routinely searched without restriction. The instant claims do not contain complicated R groups. Rather, a search of the instant peptide sequences constitutes straight sequence searching. The different

standard that the Office appears to be applying for Markush groups containing peptide structures is unsupported.

Third, the Office operates a policy wherein 10 nucleotide sequences constitute a reasonable number for examination purposes, MPEP § 803.04. This allows for the examination of up to ten independent and distinct sequences in a single application without restriction. There are no distinct limits on nucleotide sequence length and complexity in this policy, suggesting that potentially long or complicated sequences (likely longer and more complex than the 9-mer instant peptides) are considered reasonable to search. The Office also provides guidelines for the search of combinations of 10 or more individual sequences where they are claimed. In this case, the Office allows Applicants to elect a combination of ten or more sequences, which in the instant case would be 12. As stated in MPEP § 803.04:

> "If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth... More specifically, the combination will be searched until one nucleotide is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed.

Therefore, it appears that the Office readily recognizes that a search of a combination of 10 or more sequences does constitute a reasonable search and examination burden. Applicants point to the pertinent policy behind this decision in § 803.04:

> "Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of C.F.R. 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application."

Applicants assert that it is reasonable to apply a similar policy to the search of inventions containing peptide sequences, whose searches are performed similarly. This

is more reasonable than the current restriction requirement under which it is suggested that 12 peptide sequences somehow comprise 8,166 individual inventions.

The application of the above-referenced nucleotide policy can be taken to a logical conclusion with respect to the instant peptide sequences. One could suppose that the Examiner did search the 12 claimed peptide sequences, as suggested is reasonable by the standard of the nucleotide policy. One could also suppose that all 12 sequences were novel and non-obvious. If so, one could logically conclude that all combinations comprising these 12 sequences are also novel and non-obvious. Using this logic, it is difficult to envision the benefit gained by examining the individual combinations as individual inventions as suggested by the instant restriction requirement. It appears rather that the Office has already considered this possibility with respect to nucleotide sequences and has set forth a reasonable policy.

Finally, Applicants respectfully suggest that the restriction requirement be modified to include three groups related to each of 1) the compositions of claim 1 and those dependent therefrom, 2) the host cell of claim 4 and those dependent therefrom, and 3) the method of claim 9.

If this requirement is not modified and is made final by the Examiner, Applicants further reserve the right to petition from requirement for restriction under 37 C.F.R. §1.144.

**Provisional election with traverse required under 37 C.F.R. §1.143**

In compliance with 37 C.F.R. §1.143, Applicants elect with traverse Group I with a specific composition comprising SEQ ID NO. 3, SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 9, SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 15, SEQ ID NO: 17, SEQ ID NO: 19, SEQ ID NO: 21, SEQ ID NO: 23, and SEQ ID NO: 25.

## CONCLUSION

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

October 27, 2003
Date

Deborah Dugan
Attorney for Applicants
Registration No. 37,315
Telephone: (508) 270-2598
Facsimile: (508) 872-5415

GENZYME CORPORATION
15 Pleasant Street Connector
P.O. Box 9322
Framingham, Massachusetts 01701-9322

APPENDIX I



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/862,260 | 05/21/2001 | Charles A. Nicolette | GZ-210200 | 7246 |

7590 07/16/2002

Antoinette F. Konski
McCutchen Doyle Brown & Enersen LLP
3 Embarcadero Center, Suite 1800
San Francisco, CA 94111

| EXAMINER | |
|---|---|
| YAEN, CHRISTOPHER H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/862,260 | Applicant(s) NICOLETTE, CHARLES A. |
|---|---|---|
| | Examiner Christopher H Yaen | Art Unit 1642 |

*– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *40-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *40-48* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 40-42, drawn to a composition comprising immunogenic ligands, classified in class 530, subclass 324.

II. Claims 43-47, drawn to a host cell comprising immunogenic ligands and a composition comprising the host cell, classified in class 435, subclass 325.

III. Claim 48, drawn to a method of inducing an immune response with immunogenic ligands in a subject, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ one from the other because they are drawn to patentable distinct compositions that differ chemically, structurally, and functionally..

3. Inventions I-II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the products of the instant application can be used as antigens for the creation of antibodies.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

If applicant elects group I, please select one of the following SEQ ID No: 3,5,7,9,11,13,15,17,19,21, and 23 (claim 40).

If applicant elects group II, please select one of the following SEQ ID No: 5,7,9,11,13,15,17,19,21,and 23c(claim 43).

If applicant elects group III, please select one of the following SEQ ID No: 3,5,7,9,11,13,15,17,19,21, and 23 (claim 48).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 40, 43, and 48 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

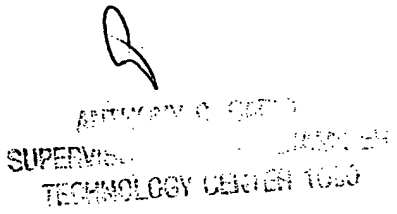
6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
July 15, 2002



APPENDIX II

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/870,089 | 05/30/2001 | Charles A. Nicolette | GZ 2099.00 | 6783 |

7590 08/22/2003

Antoinette F. Konski
McCutchen Doyle, Brown & Enersen, L.L.P.
3 Embarcadero Center, Suite 1800
San Francisco, CA 94111

| EXAMINER |
|---|
| UNGAR, SUSAN NMN |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/870,089 | Applicant(s) Nicolette |
|---|---|---|
| | Examiner Ungar | Art Unit 1642 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *May 30, 2001*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-9* are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-9 are pending in the application and are currently under prosecution.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

**Groups 1-57.** Claims 1-3 are drawn to a composition comprising at least two immunogenic ligands selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS 3, 5, 7, 9, 11, 13 classified in Class 530 subclass 300+. It is noted that the number of combination of ligands claimed is 57. The analysis to take into account each of the claimed combinations is $2^N - (N+1) = \#$ of combinations. Thus $2^6 - (6+1) = 64-7 = 57$. Applicant is required to elect a specific combination for examination. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined.

**Groups 58-114.** Claims 4-8 are drawn to a host cell/composition comprising a host cell that comprises at least two immunogenic ligands

selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS 3, 5, 7, 9, 11, 13 classified in Class 435 subclass 325+. It is noted that the number of combination of ligands claimed is 57. The analysis to take into account each of the claimed combinations is $2^N$ - (N+1) = # of combinations. Thus $2^6$ - (6+1) = 64-7 = 57. Applicant is required to elect a specific combination for examination. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined.

**Group 115- 171.** Claim 9 is drawn to a method of inducing an immune response comprising delivering a peptide composition comprising two or more immunogenic ligands selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS 3, 5, 7, 9, 11, 13 classified in Class 514 subclass 2+. It is noted that the number of combination of ligands claimed is 57. The analysis to take into account each of the claimed combinations is $2^N$ - (N+1) = # of combinations. Thus $2^6$ - (6+1) = 64-7 = 57. Applicant is required to elect a specific combination for examination. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined.

**Group 172- 228.** Claim 9 is drawn to a method of inducing an immune response comprising delivering a composition comprising a host cell which comprises two or more immunogenic ligands selected from the group consisting of 6 immunogenic ligands, wherein said ligands are SEQ ID NOS

3, 5, 7, 9, 11, 13 classified in Class 424 subclass 93.21. It is noted that the number of combination of ligands claimed is 57. The analysis to take into account each of the claimed combinations is $2^N$ - (N+1) = # of combinations. Thus $2^6$ - (6+1) = 64-7 = 57. Applicant is required to elect a specific combination for examination. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-114 as disclosed are biologically and chemically distinct, made by and used in different methods and are therefore distinct inventions.

Further, Inventions 1 through 57 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as each subcombination will produce an immune response against the native ligand, thus each subcombination has utility by itself. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for producing an immune response against the same native ligand and can be used in combination with others of the claimed

combinations in order to produce an immune response against the same native ligand. Thus the claims are distinct as required by MPEP 806.05©).

Further, Inventions 58 through114 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as each subcombination will produce an immune response against the native ligand, thus each subcombination has utility by itself. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for producing an immune response against the same native ligand and can be used in combination with others of the claimed combinations in order to produce an immune response against the same native ligand. Thus the claims are distinct as required by MPEP 806.05©).

Inventions 115-228 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Further, Inventions 115 through171 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the

patentability of the combination method does not rely necessarily and solely on the patentability of any one subcombination method as each subcombination method will produce an immune response against the native ligand, thus each subcombination method has utility by itself. Further, each of the subcombination methods has utility by itself because each of the subcombination methods are useful for producing an immune response against the same native ligand and can be used in combination methods with others of the claimed combination methods in order to produce an immune response against the same native ligand. Thus the claims are distinct as required by MPEP 806.05©).

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar
Primary Patent Examiner
August 21, 2003